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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,459	10/02/2001	Fernando DiCaprio	S63.2-10083	9616

490 7590 03/17/2004

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER
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HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 03/17/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/970,459

Applicant(s)

DICAPRIO ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Species II in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the species are so related and an extensive and burdensome search is not required. After careful reconsideration of this application, the Examiner withdraws the restriction requirement in Paper No. 9. All claims are considered at this point.

### ***Claim Objections***

2. Claim 5 objected to because of the following informalities: "the at least a portion of the stent is the stent" should be deleted. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not described in such a way as to enable one skilled in the art to

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construct and arrange the at least one membrane such that the at least one membrane retracted off the stent.

5. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the at least one sleeve retracting off the stent, does not reasonably provide enablement for at least one membrane retracting off the stent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification does not described in such a way as to enable one skilled in the art to construct and arrange the at least one membrane such that the at least one membrane retracted off the stent.

### ***Drawings***

6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the at least one membrane is constructed and arranged to be retracted off the stent must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3, and 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shull et al. (6,143,022) in view of Savin et al. (4,950,227). Shull et al. disclose a stent (9) may be made from self expanding material (col. 8, lines 48-50) and a membrane (20) disposed about the stent wherein the membrane is made from PTFE or polyurethane and has a thickness between .001 and .003 inches (col. 6, lines 44-55). Although, Shull et al. fail to disclose a catheter having sleeves for delivering the stent, attention is directed to the Savin et al. reference which discloses a stent delivering system including sleeves for securing and maintaining a reduced diameter of self expanding stent on a balloon (figs. 1-7) for delivering to a deployment site. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a delivering system having sleeves for delivering the self-expanding stent of Shull et al. in order to secure the stent to a delivery catheter and maintain its reduced diameter configuration during delivery of the stent.

In regard to claim 8 and 12, it is known in the art to employ drug into/onto a membrane covering a stent or making a stent cover including water-soluble drug in order to deliver drug to a treated site. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ drug

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into/onto a membrane covering Shull's stent in order to provide a local treatment at a treated site.

9. Claims 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herweck et al. in view of Savin et al. (4,950,227). Herweck et al. disclose a stent as claimed (5A-5B). Although, Herweck et al. fail to disclose a catheter having sleeves for delivering the stent, attention is directed to the Savin et al. reference which discloses a stent delivering system including sleeves for securing and maintaining a reduced diameter of self expanding stent on a balloon (figs. 1-7) for delivering to a deployment site. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a delivering system having sleeves for delivering the self-expanding stent of Herweck et al. in order to secure the stent to a delivery catheter and maintain its reduced diameter configuration during delivery of the stent.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho  
Patent Examiner  
Art Unit 3731  
March 7, 2004